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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,607	11/01/1999	LOUIS E. HENDERSON	15280-169300	8955

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/431,607	HENDERSON ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

The request filed on March 19, 2004 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/431,607 is acceptable and a RCE has been established. An action on the RCE follows.

Drawings

Figures 14 and 15 have been received and are accepted by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 specifies that the disulfide compound of claim 24 comprises the formula R-S-S-R. However, claim 24 has been specifically amended to exclude 5,5-Dithiobis(2-Nitrobenzoic Acid), which would comprise the required formula. Therefore, it is unclear which compounds comprising the formula are intended to be excluded from the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection maintained for reasons of record.

Applicant points to example 4 and argues that even though Table 2 in example 4 shows that DTNB cross-links NC proteins as a fast rate, the experiments were performed on purified, recombinant HIV p7NC protein and not on intact retrovirus.

A review of example 4 has been fully considered, but applicant's arguments are found unpersuasive. The disclosure clearly indicates that the results obtained using the recombinant protein are correlative with the effects using the intact virus. Page 29, line, 18 to page 30, line 22 summarize the desired cross-linking activity on intact HIV with disulfide reagents, including DTNB, see page 29, lines 27-29 and the third compound listed in Table 2 on page 33.

Applicant also asserts that Figure 15A clearly shows that DTNB (lane 5) does not cause cross-linking of NC in intact retroviruses since the NC protein is indistinguishable from the NC protein of an intact retrovirus (lane 1). For comparison, Applicant also points to lane 8 and lane 9 where the NC protein is clearly disrupted.

It is noted that the description of Figure 15 on page 9, lines 1-2, states that the figure shows "a composite figure with gel, virus inactivation, toxicity and names of compounds." A careful review of Figure 15A has been fully considered, but is found unpersuasive because it appears that the data presented in Figure 15A is inconclusive in light of Applicant's explanation. If the NC band of DTNB is indistinguishable from the NC protein of the intact NC protein from HIV, then the NC bands of sample containing tetramethylthiuram disulfide (E1b, lane 10) and tetrabutylthiuram disulfide (C4d, lane 14) are also indistinguishable from the NC derived from

intact HIV. These compounds are also listed as the first and fourth compounds, respectively, in Table 2 of the specification, which lists disulfide reagents that effectively cross-link the HIV NC protein from intact virus. The formula of tetramethylthiuram disulfide and tetrabutylthiuram disulfide would comprise R-S-S-R, recited in claim 24 and are specifically claimed in claim 25. Therefore, there appears to be a discrepancy between the results of Figure 15A indicating that tetramethylthiuram disulfide and tetrabutylthiuram disulfide worked while DTNB did not. Since it is evident from the discussion in the specification that tetramethylthiuram disulfide and tetrabutylthiuram disulfide effectively cross-link HIV NC and that the data disclosed for DTNB is equivalent regarding the presence of the NC band, it is determined that these arguments do not provide sufficient evidence to overcome the new matter rejection of record.

Applicant also points to Figure 15B and asserts that the DTNB clearly does not inactivate mature, infectious retrovirus. Applicant compares the results of DTNB with compounds asserted to have effectively inactivated the virus, i.e. Aldrithiol-2 (D1b) and Formamidine Disulfide (C4b). Applicant concludes that DTNB had no effect on infectious retroviruses.

Applicant's arguments and a careful review of Figure 15B has been fully considered, but is found unpersuasive since the symbol for DTNB falls squarely between Aldrithiol-2 (D1b) and (4-(dimethylamino)phenyl disulfide) (B2d), which effectively inactivate HIV. Further, the slope of the curve and the data in graph 15B 1 depicted for DTNB appears equivalent to the slope, curve and data depicted for the "Thiuram Disulfides", see especially tetramethylthiuram disulfide and tetrabutylthiuram disulfide illustrated in graph 15B 2.

Since it appears that the results obtained for tetramethylthiuram disulfide, tetrabutylthiuram disulfide and DTNB effectively cross-link the HIV NC protein from the data

provided in the disclosure, it is maintained that the specific exclusion of DTNB from the claims constitutes new matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-29 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-9 and 25-28 of U.S. Patent No. 6,001,555 for reasons of record. Applicant requests the rejection to be held in abeyance until allowable subject matter is indicated. Until a Terminal Disclaimer is received, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Patent Examiner, 1648